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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,201	12/20/2001	Stephen Quirk	1443.027US1	1416

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/027,201	QUIRK, STEPHEN	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/22/04, 12/20/01, 05/01/2003
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1, claims 1-6 in response to restriction requirement filed May 10, 2004 is acknowledged. The traversal is on the ground(s) that the search and examination of the claims in this case can be made without serious burden. This is not found persuasive because as stated in the previous office action the examiner established different classification between the groups. Further, while the searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 1-6.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 provides for the use of labeled proteinoid microsphere, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein et al (US 6,413,550) in view of Lee et al (US 6,191,278).

Milstein et al disclose proteinoid microspheres that are prepared by a thermal condensation reaction by heating mixtures of amino acids (col 2, lines 5-12 & col 6, line 32-40). Milstein et al discloses that the proteinoid microspheres can comprise dye reagents (labels).

Milstein et al differ from the instant invention in failing to specifically teach that the label comprises a fluorophore.

Lee et al disclose rhodamine dye reagents (fluorophore) which can be used to label microspheres or incorporated into the microspheres during their formation (col 4, lines 39-61). Lee et al discloses that the uses of these dyes labels can be used in a variety or biological and non-biological assays.

It would have been obvious to one or ordinary skill in the art to incorporate the use of rhodamine dye reagents (fluorophore) as taught by Lee et al with the microsphere of Milstein et al because Milstein et al specifically teaches the microsphere can contain a dye and Lee et al teaches that rhodamine dye reagents can be used to label microspheres or incorporated into the microspheres during their formation. Lee et al discloses that the uses of these dyes labels can be used in a variety or biological and non-biological assays, therefore a skilled artisan can have a reasonable expectation of success in incorporating the dye taught by Lee in the particles of Milstein.

8. Claims 1, 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feige et al (US 6,660,843) in view of Khoobehi et al (US 5,437,274)

Feige et al discloses proteinoid microspheres such as reported in US Patent 4,925,673). Feige et al disclose that these microspheres may contain a derivatized reagent that contains a spectral label (col 45, lines 10-37).

Feige et al differ from the instant invention in failing to specifically teach that the label comprises a fluorophore, a chemiluminescent molecule, a radioisotope, a paramagnetic ion, a metal, or an enzyme.

Khoobehi et al disclose particles which comprise a dye. Khoobehi et al disclose that the dye can be a fluorescein (fluorophore). Khoobehi et al disclose that the encapsulated dye provides for the detection of a particle or vesicle at any given time and also provides for detecting blood flow in blood vessels (col 9, lines 53-68).

It would have been obvious to one of ordinary skill in the art to incorporate a dye (label) such as taught by Khoobehi et al into the microsphere of Feige et al because Feige et al is generic with respect to the spectral label and Khoobehi et al specifically teaches that the use of this dye provides for the detection of a particle or vesicle at any given time and also provides for detecting blood flow in blood vessels. Further, spectral labels are very well known in the art.

With respect to the proteinoid microsphere comprising a mixture of amino acids that are condensed as recited in the instant claims. Since Feige et al specifically uses the same microsphere as taught by Steiner et al (US 4,925,673) (see above rejection).

Feige et al is using a microsphere which comprises a mixture of amino acids that are condensed.

9. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Milstein et al (US 6,413,550) and Lee et al (US 6,191,278) in view of Mathiowitz et al (US 5,271,961).

See above for teachings of Milstein et al and Lee et al.

Milstein et al and Lee et al differ from the instant invention in failing to teach the proteinoid microsphere is formed by thermal condensation of a mixture of amino acids in the presence of a cross linking agent.

Mathiowitz et al disclose protein microspheres that can be modified. Mathiowitz et al disclose that the modification of the protein can be done by cross-linking the protein using agents such as glutataldehyde (col 6, lines 51-62). Mathiowitz et al disclose that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, lipophilicity, molecular weight, charge and resistance to proteases (col 5, lines 50-56).

It would have been obvious to one of ordinary skill in the art to incorporate cross-linking as taught by Mathiowitz et al into the modified microspheres of Milstein et al because Mathiowitz et al shows that such modifications provides a protein having enhanced or altered thermal stability, surface reactivity, lipophilicity, molecular weight, charge and resistance to proteases.

Conclusion

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Leone-Bay et al (US 6,180,140) disclose modified amino acids used to form microspheres (col 8, lines 31-63).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary W. Counts
Examiner
Art Unit 1641
May 19, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
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05/28/04